

1. (Amended) A method of [killing] reducing the growth rate of a cell, comprising contacting [a] said cell with (a) a [p53 protein or] gene encoding a functional p53 protein and (b) a DNA damaging agent in a combined amount effective to kill said cell.
2. (Amended) The method of claim 1, wherein said cell is contacted with [a p53 protein or] said gene in combination with X-ray radiation, UV-irradiation, γ -irradiation, microwaves, adriamycin, 5-fluorouracil, etoposide, camptothecin, actinomycin-D, mytomycin C, or cisplatin.
3. (Amended) The method of claim 2, wherein said cell is contacted with [a p53 protein or] said gene in combination with cisplatin.
4. (Twice amended) The method of claim 1, wherein said cell is contacted with a recombinant[, non-viral] vector that expresses a functional p53 protein in said cell in combination with a DNA damaging agent.
5. (Twice amended) The method of claim 4, wherein said p53-expressing recombinant, non-viral vector is a naked DNA plasmid or a plasmid within a liposome, a retroviral vector, an AAV vector, or a recombinant adenoviral vector.
7. (Twice amended) The method of claim 4, wherein said p53-expressing recombinant[, non-viral] vector comprises a p53 expression region positioned under the control of a constitutive promoter.

- Q2
cont.
F2
8. (Twice amended) The method of claim 4, wherein said recombinant[, non-viral] vector comprises a p53 expression region, the cytomegalovirus IE promoter and the SV40 early polyadenylation signal.
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12. (Amended) The method of claim 1, wherein said cell is first contacted with [a p53 protein or] said gene and is subsequently contacted with [a] said DNA damaging agent.

13. (Amended) The method of claim 1, wherein said cell is first contacted with [a] said DNA damaging agent and is subsequently contacted with [a p53 protein or] said gene.

C3
F3

14. (Amended) The method of claim 1, wherein said cell is simultaneously contacted with [a p53 protein or] said gene and [a] said DNA damaging agent.

15. (Amended) The method of claim 1, wherein said cell is contacted with a first composition comprising [a p53 protein or] said gene and a second composition comprising [a] said DNA damaging agent.

F4
C4

17. (Amended) The method of claim 1, wherein said cell is contacted with a single composition comprising [a p53 protein or] said gene in combination with [a] said DNA damaging agent.

19.¹⁹ (Amended) The method of claim ~~17~~¹⁶, wherein said cell is contacted with a single composition comprising a recombinant vector that expresses p53 in said cell in combination with [a] said DNA damaging agent.

C5
20.¹⁹ (Amended) The method of claim ~~19~~¹⁸, wherein said cell is contacted with a single composition comprising a recombinant adenovirus containing a recombinant vector that expresses p53 in said cell in combination with [a] said DNA damaging agent.

Sub
F6
22. (Amended) The method of claim ~~21~~, wherein said tumor cell is a malignant cell.

23.²¹ (Amended) The method of claim ~~22~~²⁰, wherein said malignant cell is a lung cancer cell.

24.²² (Amended) The method of claim ~~22~~²⁰, wherein said malignant cell is a breast cancer cell.

C6
25.²³ (Amended) The method of claim ~~22~~²⁰, wherein said malignant cell has a mutation in a p53 gene.

Sub
F6
26. (Twice amended) The method of claim 21, wherein said tumor cell is located within an animal at a tumor site [and said p53 protein or gene and DNA damaging agent are administered to the animal in a pharmacologically acceptable form].

- F7
C7
32. (Amended) A composition comprising a [p53 protein or] gene encoding a functional p53 polypeptide in combination with a DNA damaging agent.
33. (Amended) The composition of claim 32, comprising [a p53 protein or] said gene in combination with adriamycin, 5-fluorouracil, etoposide, camptothecin, actinomycin-D, mitomycin C, or cisplatin.
34. (Amended) The composition of claim 33, comprising [a p53 protein or] said gene in combination with cisplatin.
35. (Amended) The composition of claim 32, comprising a recombinant vector that expresses a functional p53 protein in an animal cell in combination with a DNA damaging agent.

- C8
- 42.³⁴ (Amended) A therapeutic kit comprising, in suitable container means, a pharmaceutical formulation of a recombinant vector that expresses a functional p53 protein in an animal cell and a pharmaceutical formulation of a DNA damaging agent.

- Sub
F10
C9
77. (Amended) The method of claim 4, wherein said [vector] gene is administered prior to said DNA damaging agent.
78. (Amended) The method of claim 4, wherein said [vector] gene is administered after said DNA damaging agent.

CA
cont
F10
cont

79. (Amended) The method of claim 4, wherein said [vector] gene is administered at the same time as said DNA damaging agent.

Sub
F11

83. (Amended) The method of claim [28] 26, wherein said [vector] gene is delivered endoscopically, intravenously, intratracheally, intralesionally, percutaneously or subcutaneously.

84.⁵⁸ (Amended) The method of claim [28] 26²⁴, wherein said tumor site is a resected tumor bed.

85.⁵⁹ (Amended) The method of claim [28] 26²⁴, wherein said administration is repeated.

Sub
C10
F12

86. (Amended) The method of claim [81] 13, wherein the period between administration of the DNA damaging agent and [vector] gene is between 12 and 24 hours.

87. (Amended) The method of claim [81] 13, wherein the period between administration of the DNA damaging agent and [vector] gene is between 6 and 12 hours.

88. (Amended) The method of claim [81] 13, wherein the period between administration of the DNA damaging agent and [vector] gene is about 12 hours.

89. (Amended) The method of claim [80] 12, wherein the period between administration of the [vector] gene and DNA damaging agent is between 12 and 24 hours.

90. (Amended) The method of claim [80] ¹², wherein the period between administration of the vector and DNA damaging agent is between 6 and 12 hours.

91. (Amended) The method of claim [80] ¹², wherein the period between administration of the vector and DNA damaging agent is about 12 hours.

96. ⁶⁶ (Amended) The method of claim [28] ²¹, wherein said tumor cell is an epithelial tumor cell.

97. ⁶⁷ (Amended) The method of claim [95] ²³, wherein said lung cancer cell is non-small cell lung carcinoma cell.

111. ⁷² (Amended) The method of claim [28] ²⁶, wherein said [vector] gene is administered in about 0.1 ml.

112. ⁷³ (Amended) The method of claim [28] ²⁶, wherein said [vector] gene is administered in about 10 ml.

127. (Amended) The method of claim [7] ⁴, wherein said promoter is a [constitutive] promoter.

128. ⁴⁰ (Amended) The method of claim [127] ⁷, wherein the promoter is selected from the group consisting of SV40, CMV and RSV.